

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/068,114	DAUGAN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Tamthom N. Truong	1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment of 01-16-04.
2. ☒ The allowed claim(s) is/are 19 and 20.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                       |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date 3 | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                 | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|  | 9. <input type="checkbox"/> Other _____.  |

***Examiner's Amendment***

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

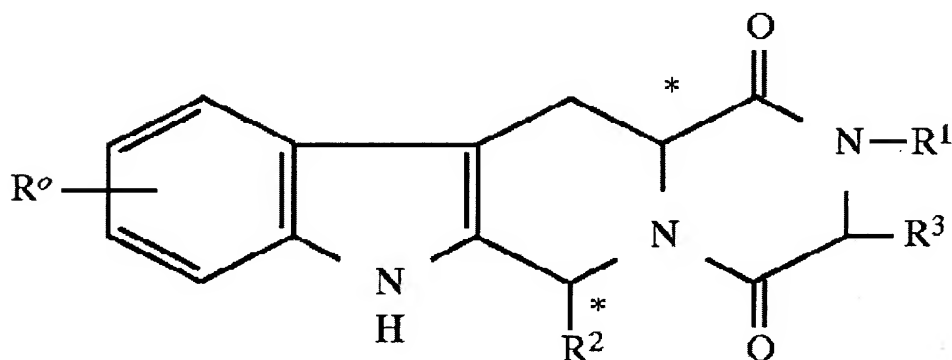
Authorization for this examiner's amendment was given in a telephone interview with Mr. James Napoli on 04-12-04, and 04-14-04.

The application has been amended as follows:

Replace the amended claim 19 with the following:

Claim 19. A method of treating a vascular disease comprising administering to a human or nonhuman body the following:

- a) an endothelium-derived relaxing factor, an atrial natriuretic factor, a brain natriuretic peptide, a C-type natriuretic peptide, or an endothelium-dependent relaxing agent, and
- b) a therapeutically effective amount of a compound having a formula of



(I)

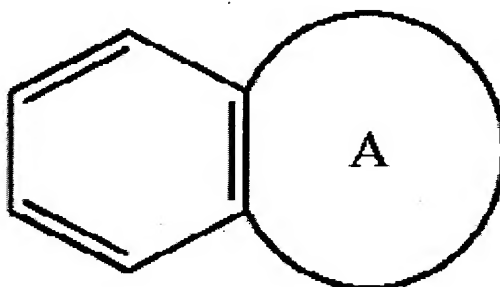
or salts or solvates thereof, in which:

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$R^0$  represents hydrogen, halogen, or  $C_{1-6}$ alkyl;

$R^1$  represents hydrogen,  $C_{1-6}$ alkyl,  $C_{2-6}$ alkenyl,  $C_{2-6}$ alkynyl, halo $C_{1-6}$ alkyl,  $C_{3-8}$ cycloalkyl,  $C_{3-8}$ cycloalkyl $C_{1-3}$ alkyl, aryl $C_{1-3}$ alkyl, wherein aryl is phenyl or phenyl substituted with one to three substituents selected from the group consisting of halogen,  $C_{1-6}$ alkyl,  $C_{1-4}$ alkoxy, methylenedioxy, and mixtures thereof, or heteroaryl $C_{1-3}$ alkyl, wherein heteroaryl is thienyl, furyl or pyridyl, each optionally substituted with one to three substituents selected from the group consisting of halogen,  $C_{1-6}$ alkyl,  $C_{1-6}$ alkoxy, and mixtures thereof;

$R^2$  represents an optionally substituted monocyclic aromatic ring, selected from benzene, thiophene, furan, and pyridine, or an optionally substituted bicyclic ring



attached to the rest of the molecule via one of the benzene ring carbon atoms and wherein the fused ring A is a 5- or 6-membered ring which may be saturated or partially or fully unsaturated and comprises carbon atoms and optionally one or two heteroatoms selected from oxygen, sulfur, and nitrogen; and

$R^3$  represents hydrogen or  $C_{1-6}$ alkyl, or  $R^1$  or  $R^3$  together represent a 3- or 4-membered alkyl or alkenyl chain component of a 5- or 6-membered ring.

*Allowable Subject Matter*

2. Claims 19 and 20 allowed. The above Examiner's amendment has obviated the previous rejections of 112/1<sup>st</sup> and 2<sup>nd</sup> paragraphs.

*Reason for Allowance*

3. The following is an examiner's statement of reasons for allowance:

The closest reference is **Demerson et. al.** (US 4,273,773) which teaches the possibility of a tetracyclic compound when R<sup>3</sup> and R<sup>4</sup> form a -OCH<sub>2</sub>O- chain. However, the instant compound does not have a ring formed by -OCH<sub>2</sub>O-. Furthermore, Demerson et. al. does not teach a combined formulation as claimed herein. Thus, the teaching of Demerson et. al. does not anticipate or render obvious the claimed method of treatment.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-T (~10 am ~ 8:30 pm) starting from February 22<sup>nd</sup>, 2004.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

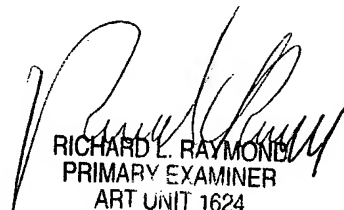
The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

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April 14, 2004



RICHARD L. RAYMOND  
PRIMARY EXAMINER  
ART UNIT 1624